

EU Declaration of Conformity

According to Annex IV of the Regulation (EU) 2017/745 concerning medical devices, we:

Manufacturer name: Delmont imaging
Manufacturer address: 390 avenue du Mistral, 13600 La Ciotat, FRANCE
Manufacturer SRN: FR-MF-000000157

Declare under our responsibility (see list in annex for details and accessories):

Generic device name: Resection chips extractor
Risk classification: I, sterile, rule 1
Basic UDI-DI: 37012178CLVIHR

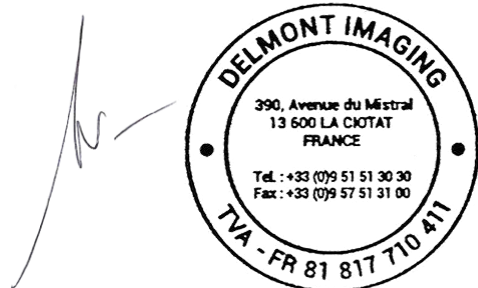
Based on the following elements:

Conformity route: Annex II, III and IX the European Regulation (EU) RG 2017/745
Technical file: TF-CLVI
Notified body: SIQ (1304), Mašera-Spasićeva ulica 10, SI-1000 Ljubljana, Slovenia
EC certificate: N° MDR-0032
Valid until: 2030-10-16

We certify and declare that the medical device specified above complies with the requirements of:

- the European Regulation (EU) RG 2017/745, of the European Parliament and of the Council of 5 April 2017 on medical devices,

Name: MONTILLOT Pierre
Function: CEO
Revision date: 2025-10-17
Date of validity: 2030-10-16



Applicable standards

EN 62366-1:2015 +A1:2020; EN ISO 10993-2:2022; EN ISO 13485:2016 +AC:2018 +A11:2021; EN ISO 14971:2019 +A11:2021; EN ISO 15223-1:2021; EN ISO 20417:2021; EN ISO 11135:2014 +A1:2019; EN ISO 11607-1:2020 +A11:2022 +A1:2023; EN ISO 11607-2:2020 +A1:2023; EN ISO 10993-7:2008 +A1:2022; EN ISO 10993-1:2020; EN 556-1:2024

REF	UDI-DI	Description
D110 200 000	03701217808744	Sterile resection chips extractor. Single use only.